



Economic Impact Analysis Virginia Department of Planning and Budget

12 VAC 5-230 –Certificate of Public Need State Medical Facilities Plan Virginia Department of Health August 11, 2004

The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with Section 2.2-4007.G of the Administrative Process Act and Executive Order Number 21 (02). Section 2.2-4007.G requires that such economic impact analyses include, but need not be limited to, the projected number of businesses or other entities to whom the regulation would apply, the identity of any localities and types of businesses or other entities particularly affected, the projected number of persons and employment positions to be affected, the projected costs to affected businesses or entities to implement or comply with the regulation, and the impact on the use and value of private property. The analysis presented below represents DPB's best estimate of these economic impacts.

Summary of the Proposed Regulation

The proposed changes will significantly edit and reorganize the State Medical Facilities Plan regulations to improve clarity. The proposed changes will also relax many of the measurable criteria used in assessing the public need for the proposed projects while making a number of criteria more stringent.

Estimated Economic Impact

The proposed regulations contain rules for the State Medical Facilities Plan (SMFP) component of the Certificate of Public Need (COPN) program. SMFP is one of the 20 criteria used in evaluating a COPN application, but it has a significant impact on approval/denial decisions. Under the COPN program, a certificate is required before expanding certain medical services, or creating a new facility. SMFP establishes facility need projection methodologies and project review standards. These medical services include general acute care services, perinatal services, diagnostic imaging services, cardiac services, general surgical services, organ transplantation services, medical rehabilitation services, lithotripsy services, miscellaneous

capital expenditures, and nursing facility services. Even though the proposed changes are exclusively about the SMFP rules, analysis of their economic effects would be incomplete without the thorough understanding of the issues surrounding the COPN program.

A brief history of the Virginia's COPN program is provided in a 1997 report of the Virginia Joint Commission on Health Care. According to this report, the Virginia COPN program was established in 1973 primarily as a response to 1972 amendments to the federal Social Security Act, which allowed the federal government to deny reimbursement under Medicare, Medicaid, and Child Health Programs for capital projects that are found to be inconsistent with the plans of designated state planning agencies. In 1974, the National Health Planning and Resources Development Act (NHPRDA) mandated all states to develop a COPN program by 1980. Later, in 1988, the role of federal government was eliminated with the expiration of NHPRDA. However, 36 states, including Virginia, still maintain their COPN programs.¹

The Virginia COPN program is administered by the Department of Health in cooperation with five regional planning agencies (Health System Agencies). Projects are first evaluated at the regional level and then considered at the state level. The commissioner of health is in charge of making the final decisions. Adverse decisions could be appealed through the court system. The decisions of the commissioner must be consistent with the SMFP or the commissioner must find the SMFP outdated. Based on the amendments to the COPN law in 1998, the commissioner may condition approvals on the provision of free or reduced rate care to indigents, the acceptance of patients with special needs, or the facilitation of primary care for underserved areas.

In 2000, the General Assembly, through Senate Bill 337, required the Joint Commission on Health Care to develop a plan to eliminate the COPN program by July 2004. The deregulation plan was a "fragile" consensus among the stakeholders and contained several provisions for the support it needed. This fragile consensus was contingent upon provisions requiring the Commonwealth to provide \$135 million funding from the general fund for (i) indigent care at academic health centers, (ii) increased Medicaid access to the adult parents, the aged, and the disabled, (iii) undergraduate medical education, (iv) increased Medicaid

¹ Between 1989 and 1992 specialty services, non-hospital facilities, specialized medical equipment, and other capital expenditures were deregulated.

reimbursement to hospitals, (v) increased reimbursement to physicians, and (vi) increased state matching dollars for indigent health care trust fund. Probably because of significant fiscal implications, the deregulation plan has not been approved and implemented by the General Assembly.

Economics of the COPN program:

Issues surrounding the COPN program can be grouped under medical care costs, quality, access, and charity care. Economic analysis of Virginia's COPN on each one of these variables requires extensive resources which are beyond the scope of this analysis. Even if significant resources are devoted for this purpose, we suspect that such an analysis would be unable to produce conclusive evidence on every facet of the COPN program and be of little practical importance due to data limitations. Instead, we rely on the economic theory and readily available empirical evidence to assess likely costs and benefits of the COPN program in Virginia.²

Costs. The initial driving force for the COPN programs, in addition to the 1974 federal mandate, appears to be the concern that excess capacity and capital investment contributed to publicly funded medical care costs, as early 1970s health care payments were based on cost-based reimbursement methodologies. Under cost-based reimbursement methodologies, providers were being reimbursed for their capital costs and had incentives to build excess capacity.

Since the inception of COPN programs, many changes occurred in health care financing and delivery rendering most of the fiscal benefits expected from COPN obsolete in today's market place. A significant change is the shift from cost-based reimbursement methodologies toward service-based payment methodologies. Many private health care insurance companies as well as large public programs such as Medicare and Medicaid adopted service based payments methods such as inpatient prospective payment system, diagnostic related groups, resource utilization groups, outpatient prospective system, ambulatory payment classification system, and managed care capitation rates over the last two decades. The trend toward service-based payments reduced provider incentives to build excess capacity or take on unneeded capital

² Empirical findings are primarily obtained from the State of Washington Joint Legislative Audit and Review Committee, 1999, literature review to minimize research costs.

investment projects, as they cannot directly recover the cost of their investments. Thus, this concern does not seem to have validity in today's health care market as it did 30 years ago.

Additionally, proponents argue that COPN programs lead to fewer, larger firms to provide services, which in turn reduces cost of care. So, in the absence of COPN programs, we could see an increase in health care costs. This argument suggests that large health care firms produce services at lower average costs due to increased plant size, which is a well-known possibility in economics, termed as "economies of scale." While economies of scale may well exist in production of some health care services over certain plant sizes, generalizing this possibility for all services covered under the COPN programs and for any quantity of production is bound to be wrong.

Even for those services where there are economies of scale, forcefully leading fewer firms to produce more output through the COPN program has certain social costs. These social costs should be weighed against the benefits expected from lower average production costs. These social costs stem from restricting entry into an otherwise competitive market. Under the COPN umbrella, incumbents are protected against competition from new entrants. Firms with significant market power are well known to charge prices that maximize their revenues rather than those reflect their average costs. And, prices charged definitely exceed the average cost of production if the firm is to make above normal profit, which is the case in a non-competitive market.

In addition, the revenue-maximizing output level is known to be lower and the revenue-maximizing price is known to be higher than what it would be if entry were not restricted. In other words, if entry is limited through COPN, providers are likely to offer less and charge more. This profit maximizing behavior in the absence of competition takes welfare away from consumers and channels it to the providers and creates significant efficiency losses, known as "deadweight losses,"³ for the whole economy. A recent study by the Federal Trade Commission and the Department of Justice in 2004 goes on to state that these two agencies "...believe that CON programs can pose serious competitive concerns that generally outweigh CON programs'

³ "Deadweight losses" occur because a distortion to the market mechanism (such as restricting competition through the COPN program) takes welfare away from suppliers and buyers and no one in the economy receives them. In other words, it is the net loss in economic welfare that occurs due to distortions in the market. Thus, everyone could be better off if the distortion is removed.

purported benefits. Where CON programs are intended to control health care costs, there is considerable evidence that they can actually drive up prices by fostering anticompetitive barriers to entry.”

In short, the claim that leading fewer firms to produce more reduces cost of health care is not well founded because (i) lower average production costs does not necessarily mean the prices providers charge will be lower, (ii) quite the contrary, firms shielded from competition charge higher prices and produce less than optimal quantities, and (iii) other costs of COPN such as transferring welfare from consumers to providers and deadweight efficiency losses likely exceed any savings expected from COPN.

Another source of social costs that seems to escape the attention of most is the inefficiencies created by ignoring the economies of scope that may exist in health care production. Economies of scope occur when production of one good creates savings for production of another good. In such cases, production costs are lower when the two goods are produced together than produced separately. Because the COPN review criteria focus on volume and capacity but does not directly take into account the other types of services already provided in conjunction with the service for which approval is sought, it is more than likely that the COPN program forgoes some potential savings that would be realized if entry into the market were not restricted.

Empirical research does not appear to support the claim that COPN reduce health care costs. COPN is not found to be effective in controlling overall per capita health care spending because many factors affecting costs such as labor and physician services are beyond the scope of the COPN programs. Also, COPN is not found to be effective in controlling hospital costs because (i) not all services are regulated under COPN, (ii) COPN is not always effective controlling supply, and (iii) when bed supply was controlled expenditures per bed are found to increase. [Arnold and Mendelson, 1992; Delaware Health Commission, 1996; Conover and Sloan, 1998; Custer, 1997; Lanning et al., 1991; Mendelson and Arnold, 1993; Salkever, 1978].

Quality. Proponents argue that COPN programs improve quality of care because (i) COPN causes high utilization of medical equipment or services leading to better outcomes, (ii) it helps filter good providers by screening quality records and by judging their ability to meet conditions associated with quality care, (iii) it helps stabilize health care market by filtering out financially

unsound or professionally unprepared providers, and (iv) it restrains growth of for-profit providers that may offer lower quality care.

It is probable that COPN could improve quality of care through these channels with the exception of (iv). However, it is a wasteful way trying to improve quality of care through the COPN program. It is important to notice that the primary reason behind the COPN program is not that it would improve quality but rather that it would contain costs in a cost-based payment environment and that it was mandated by federal legislation. Thus, improved quality should be evaluated as a secondary unintended benefit associated with COPN programs. If the object of a regulation were to improve quality of care, it would have never been done the way COPN does it. In this sense, COPN is not a necessary program to assure quality of care. Other approaches directly targeting quality of care as the primary goal would probably be economically more efficient. There are already some quality safeguards in place. For example, dissemination of health care information to consumers mitigates potential quality of care risks through the market mechanism. Also, there are various government programs to monitor quality of care in the absence of the COPN program. These include facility licensure programs and Medicare and Medicaid certification programs. Perhaps, tailoring these existing mechanisms to bolster quality would be much more cost effective in protecting public health and safety rather than relying on very questionable COPN spillover quality improvements.

Furthermore, COPN could have adverse effects on quality by slowing the diffusion of technology, by protecting low-quality providers, and by preventing innovative providers entering the market. For instance, one can easily argue that if the equipment is outdated or the staff is incompetent, a COPN program may be forcing more consumers to take risks they would not be otherwise willing to take. Thus, limitations COPN places on consumer choice may not be in the best interest of the public.

Empirical findings on the quality aspect of COPN appear to be mixed. Evidence is inconclusive regarding the ability of COPN in improving quality by forcing high utilization of equipment or services even though high utilization is found to improve outcomes. There is some evidence that COPN protects quality in the home health sector by filtering out unprepared or unqualified providers. COPN's effect on keeping out for-profit providers and resulting effects on quality are mixed. Finally, findings indicate that COPN does not provide an ongoing

mechanism for monitoring quality. [Arnold and Mendelson, 1992; Brown et al., 1992; Collins and Keane, 1997; Conover and Sloan, 1998; Deemez et al., 1992; Delaware Health Care Commission, 1996; Federal Trade Commission, 1986; Griffiths et al., 1994; Lanning et al., 1991; Lewin/ICF and Alpha Center, 1991; Luft and Garnick, 1990; National Home Care Association Newsletter, 1998; Irvin, 1998; Burling, 1998; U.S. General Accounting Office, 1998].

Access. Proponents of the COPN program argue that the program improves access to health care (i) by limiting entry of new providers who may undermine the ability of incumbents to provide unprofitable services, (ii) by restricting expansion of facilities in overbuilt areas leading providers to expand services in underserved areas, and (iii) by requiring providers to serve all patients needing care in a particular geographic area. Again, it is generally unlikely that the COPN program could be effectively used to improve access to care. COPN is simply a wasteful way of trying to improve access. Based on economic theory, it can be reliably inferred that economic costs associated with trying to improve access through the COPN would far outweigh any ancillary access benefits.

Preventing entry of new competitors so that incumbents could continue to provide unprofitable services such as trauma or burn units, amounts to financing of such unprofitable operations through above normal profits the incumbents are allowed to make under the COPN umbrella. While many examples could be offered, teaching hospitals' status in Virginia is a particularly interesting case given their ability to shift costs. Teaching hospitals are able to collect revenues from high technology services under the COPN umbrella to make up their losses from providing uncompensated indigent care. If ownership were not restricted, new entrants would offer these lucrative revenue-generating services, thereby acerbating teaching hospitals' losses. Thus, the COPN program shields teaching hospitals from competition and allows them to finance the cost centers by the revenue centers.

In this particular case, while proponents may argue COPN improves access to indigent, this mechanism distorts the prices of high technology revenue generating services upward, causes under consumption of these services by paying consumers, and results in inefficient allocation of resources. Economic theory predicts that such social costs would far outweigh the social benefits that can be expected from improved access. Furthermore, the economic theory suggests that in such cases it is best to address the market failure (i.e. provision of unprofitable

services in this example) through direct payments and allow the remaining market forces to operate with no intervention.

In general, similar conclusions apply to other cases where COPN is used as a non-market tool to enhance access to care.

The empirical evidence on the access aspect of COPN appears to be limited and conflicting. In some cases, COPN is found to protect inner city facilities and enhance access while in some other cases COPN may have restricted needed services as the opponents argue would happen. Also, access effects seem to vary from state to state and from service to service. Finally, there appears to be lack of empirical evidence to understand the rural access effects of COPN. [Arnold and Mendelson, 1992; Brown et al, 1992; Delaware Health Care Commission, 1996; Hackey, 1993; Kiel, 1993; Lewin/ICF and Alpha Center, 1991; McGinley, 1995; Mendelson and Arnold, 1993; Rettig, 1992; Sloan, 1988; Weaver, 1995].

Charity Care. Proponents argue that COPN enhances provision of charity care (i) by explicitly requiring a certain level of charity care as a condition of approval, (ii) indirectly by improving the profit margins of existing providers, (iii) by preventing new entrants who would “cherry pick” lucrative services, and (iv) by favoring not-for-profit providers who would provide more charity care.

In Virginia, the COPN program is used as a tool to provide incentives to providers to offer services to indigent patients at reduced rates through the conditioning process adopted in 1988. In fact, there are claims made by some researchers that the implicit purpose of the COPN program is to issue licenses and restrict competition to create an incentive to provide care to the indigent rather than to prevent duplication of services and investment in costly excess capacity.

This conditioning process was created as a response to findings that the burden of uncompensated care is shared unevenly among the hospitals and there was no mechanism to correct this inequality. The 1988 General Assembly introduced the conditioning process into the COPN program and at the same time created the Indigent Health Care Trust fund to more evenly distribute the uncompensated care burden. With the conditioning mechanism, the state would be able to ensure provision of services to the indigent and uninsured who may have otherwise experienced difficulties with access to care if the intent of a provider were to prioritize paying patients.

The conditioning of certificates can be characterized as a mechanism that allows entry into an otherwise restricted market in exchange for providing uncompensated care. In economic terms, certificate holders are allowed to make above normal profits in the health care market and then required to use some of these proceeds to finance health care for the indigent and the uninsured. Even though it may be difficult to find out whether these above normal profits are commensurate with the cost of uncompensated care provided, economic theory unambiguously predicts that such mechanism would be less efficient compared to financing of uncompensated care through direct payments. In other words, the society as a whole would be better off (particularly given the transfer of welfare from consumers to providers and the deadweight efficiency losses as discussed earlier) if the conditioning mechanism is abandoned and uncompensated providers are paid directly.

Empirical evidence indicates that COPN programs initially screen for the likelihood of a facility providing charity care, but do not monitor ongoing compliance. There is some evidence showing that some states are more likely to approve providers offering more charity care. While COPN's effect on favoring not-for-profit providers is conflicting, evidence suggests that for-profits tend to provide less charity care, and public and teaching hospitals provide the most charity care. Some evidence shows that COPN improves operating margins of existing providers, which may lead to increased charity care. [Campbell and Ahern, 1993; Campbell and Fournier, 1993; Conover and Sloan, 1998; Hackey, 1993; Lanning et al., 1991; Lewin/ICF and Alpha Center, 1991; Mendelson and Arnold, 1993; Pennsylvania Legislative Budget and Finance Committee, 1996].

Summary. COPN programs emerged during 1970s as a response to a federal mandate introduced by the National Health Planning and Resources Development Act (NHPDA) and to health care cost containment concerns associated with cost-based reimbursement methodologies. In today's environment, none of these original reasons seem to have validity as they did three decades ago. In 1988, when NHPDA expired, COPN programs were no longer federally mandated. Also, the trend toward service-based payment methodologies coupled with expansion of managed care significantly mitigated the original cost containment concerns that existed when cost-based payment methodologies were being used. Finally, most empirical research has failed to find support for the claim that COPN programs reduce health care costs.

While these developments were taking place, several ancillary benefits seem to have emerged as primary justifications for the continued existence of these regulatory programs. This view severely suffers from several shortcomings. First, theoretically it is just as easy to conjecture that COPN programs could reduce quality, access, and charity care. In fact, empirical evidence on these matters is mixed showing both negative and positive effects. Second, economic theory unambiguously predicts that the use of COPN as an indirect mechanism to improve quality, access, and charity care is inferior to the use of direct mechanisms addressing the same issues. Finally, while COPN may produce some ancillary benefits, it channels significant welfare from consumers to providers, and creates economic inefficiencies known as deadweight losses. Thus, maintaining the COPN program for highly speculative and unreasonable ancillary benefits that may or may not occur is a waste of society's resources.

The balance of economic theory and empirical findings suggest that the repeal of the COPN program and simultaneous adoption of other regulatory programs directly addressing quality, access, and charity care issues would produce net economic benefits for the Commonwealth. The Federal Trade Commission and the Department of Justice further support this conclusion by urging "states with CON programs to reconsider whether they are best serving their citizen's health care needs by allowing these programs to continue." [Federal Trade Commission and the Department of Justice, 2004].

Proposed changes to SMFP:

As mentioned, SMFP is one of the 20 criteria used in evaluating a COPN application. It establishes facility need projection methodologies and project review standards. Numerous proposed changes will significantly reorganize the regulations by eliminating redundant sections, by combining duplicative sections, by deleting philosophical and irrelevant statements, and by adding new sections. These changes are primarily editorial and are not expected to create any significant economic effects, but are expected to improve the clarity of the regulations. Improved clarity would probably streamline the application process, reduce potential confusions, and produce some economic benefits in terms of administrative cost savings, avoided delays, or communication costs.

More importantly, the proposed changes will revise a significant number of measurable criteria established in the regulations. These criteria are used to evaluate the need for a proposed

facility, equipment, or project and play a crucial role in approval/denial decisions. The majority of changes will lead to less restrictive distance, occupancy, and volume standards in following service areas: inpatient hospitals/beds, obstetrical services/beds, intermediate care facilities for mental retardation, introduction of open-heart surgery at an existing facility, nursing homes/beds, diagnostic imaging, radiation therapy, cardiac catheterization, lithotripsy.⁴ In general, these less restrictive measurable criteria are expected to allow i) approval of facilities with lower occupancy rates, ii) approval of services or bed capacity for lower projected patient volume or sick population, iii) approval of more services or relocation of beds in a wider geographical area, iv) approval of projects for lower number of projected procedures, v) approval of services more accessible to population in the planning districts, vi) approval of services with less negative volume impact on existing programs, vii) approval of facilities with smaller capacity, viii) approval of more equipment in a planning district, ix) approval of additional equipment with lower past utilization rates, and xi) approval of equipment based on projections with less restrictive assumptions.

On the other hand, the proposed changes will require higher volumes and survival rates to establish an organ transplant program. The department notes that the increased minimum volume requirements improve the outcomes, recent techniques improve the survival rates, and these standards are advocated by several national organizations. However, if higher utilization leads to better outcomes in transplantation services, this could be accomplished by other direct mechanisms outside the COPN framework in order to avoid economic losses associated with this program.

Additionally, the proposed changes will make some aspects of SMFP more stringent in service areas where the proposed changes are expected to result in less restrictive approval criteria on net. These include i) requiring higher projected patient volume or sick population in order to establish a rehabilitation hospital, addition of rehabilitation beds, or introduction of rehabilitation services at an existing facility, ii) reducing nursing bed capacity allowed in an existing acute care facility from 20% to 10% of the number of non-nursing home beds, iii) removing an alternate methodology which can be manipulated by the applicant to calculate the number CT scans for new or existing facilities, iv) increasing the volume standards for MRIs for

⁴ See appendix for a detailed list of proposed changes to measurable criteria.

new or existing facilities, v) establishing a minimum annual patient volume standard for cardiac cauterization services at an existing facility, and vi) establishing a proximity standard and increasing the threshold number of referrals for lithotripsy services.

According to the Virginia Department of Health, approximately 522 (86%) applications were approved out of 608 over the last 8-year period. Even though a number of the proposed changes are more restrictive than the current requirements, majority of changes with the exception of changes affecting organ transplant services, are less restrictive. Thus, on average, the proposed standards should make the issuance of COPN easier for applicants. Less stringent quantitative criteria are expected to cause a small number of applicants to come forward who would not have under somewhat stricter SMFP criteria. We may see a small increase in applications in service areas where the proposed standards are less restrictive. However, a reliable estimate for the potential increase in applications is not available, as this would require extensive resources to develop.

Since the number of approvable projects in certain service areas is likely to increase, this could be seen as less restrictive entry requirements into regulated service areas. To the extent the proposed changes makes the issuance of a COPN less stringent, the economic effects would be akin to those of COPN discussed earlier. Based on the available empirical literature, we should expect no significant changes in healthcare costs and charity care. We could also see some negative or positive effects on quality and access varying from one service type to another. However, as restrictions on competition are reduced, we would expect a reduction in the welfare transferred from consumers to producers and a reduction in the economic inefficiencies embedded in the COPN program. Provided that the potential negative effects on quality, access, and charity care are negligible, or are addressed through other direct mechanisms, resulting ease of entry should produce net substantial economic benefits.⁵ The size of the net economic benefits expected from less restrictive SMFP standards are probably very small compared to the size of net benefits that would be realized if the COPN program were deregulated as envisioned by Senate Bill 337 of the 2000 General Assembly.

⁵ On the contrary, net economic costs are expected for organ transplant services for which more restrictive measurable criteria are proposed.

Businesses and Entities Affected

The proposed regulations apply to nursing facilities, hospitals, and other medical facility providers. Current inventory of regulated facilities/beds/equipment include 40 outpatient surgical hospitals, 273 nursing homes, 13 freestanding diagnostic imaging facilities, 83 general hospitals, 2 rehabilitation hospitals, 8 freestanding radiation therapy facilities, 2 long-term acute care hospitals, 21 ICF/MR facilities, 1 freestanding cardiac catherization center, 5 psychiatric hospitals, 1 freestanding substance abuse treatment facility, 32,607 nursing home beds, 18,640 acute care beds, 1,762 psychiatric beds, 557 ICF/MR beds, 738 operating rooms, 79 cardiac catherization labs, 305 computed tomography scanners, 117 magnetic resonance imaging scanners, 4 positron emission tomography scanners, 51 radiation therapy equipment, 21 lithotripsy equipment, 18 open-heart surgery programs, and 6 organ transplant programs. Approximately, 100 applications for regulated services are reviewed each year. Additionally, these regulations affect five Health System Agencies as well as indigent and non-indigent patients receiving services from regulated providers.

Localities Particularly Affected

The proposed regulations apply throughout the Commonwealth. However, a locality may be particularly affected if it chooses to own or operate a regulated facility, as the facility would be subject to these regulations.

Projected Impact on Employment

The proposed regulations are expected to slightly increase the number of providers seeking approval. As they start providing services, they would hire new medical and support personnel contributing to the employment in Virginia. Whether these new facilities/services would significantly affect the employment by current providers is not known.

Effects on the Use and Value of Private Property

The proposed regulations are not expected to have an effect on the value of physical private property. However, by allowing more providers to operate services already regulated or by allowing providers to offer new services, the proposed regulations are expected to contribute, on average, to value of medical businesses in the Commonwealth. Whether the increased

number of providers in the market would significantly affect the value of existing medical businesses is not known.

Related Literature

- Arnold, Judith and Daniel Mendelson, (Lewin ICF) "Evaluation of the Pennsylvania Certificate of Need Program," submitted to the Pennsylvania Legislative Budget and Finance Committee, April 1992.
- Brown, Eric, J. Douglas Smith, and Jody Sindelar, "Can We Regulate the Quality of Care?: The Case of Dialysis in Connecticut," *American Journal of Kidney Diseases*, Vol. XIX, No. 6, 1992.
- Burling, Stacey, "New Jersey Minimums of Bypass Surgery May be Up in July," *Philadelphia Inquirer*, April 26, 1998.
- Campbell, Ellen S., and Gary M. Fournier, "Certificate-of-Need Deregulation and Indigent Hospital Care," *Journal of Health Politics, Policy, and Law*, Vol. 18, No. 4, Winter 1993.
- Campbell Helen S., and Melissa W. Ahern, "Have Procompetitive Changes Altered Hospital Provision of Indigent Care?," *Health Economics*, Vol. 2, 1993.
- Collins, A. J. Ma, W. Keane, (research abstract), "Reuse of Hemodialyzers: Is there a Risk in 1994?," *Nephrology Dialysis Transplantation*, Vol. 12 no. 9, 1997.
- Conover, Christopher, and Frank A. Sloan, "Does Removing Certificate-of-Need Regulations Lead to a Surge in Health Care Spending?," *Journal of Health Politics, Policy, and Law*, Vol. 23, No. 3, June 1998.
- Delaware Health Care Commission, Cost Containment Committee, "Evaluation of Certificate of Need and Other Health Planning Mechanisms," Volume I: Final Report; and Volume II, Technical Appendices, May 1996.
- Custer, William S., Ph.D., "Certificate of Need Regulation and the Health Care Delivery System," Center for Risk Management and Insurance Research, Georgia State University, February 1997.
- Deemez, James A., David W. Windus, and the St. Louis Nephrology group, "Hemodialysis Prescription and Delivery in a Metropolitan Community," *Kidney International*, Vol. 41, 1992.
- Federal Trade Commission, "Certificate of Need Regulation of Entry Into Home Health Care Markets," Washington, D.C., 1986.
- Federal Trade Commission and the Department of Justice, "Improving Health Care: A dose of Competition," July 2004.
- Griffiths, Robert I., Neil R. Powe, Darrell J. Gaskin, Gerard F. Anderson, Gregory V. de Lissovoy, and Paul K. Whelton, "The Production of Dialysis by For-Profit versus Not-

- For-Profit Freestanding Renal Dialysis Facilities,” *Health Services Research*, Vol. 29 No. 4, October 1994.
- Hackey, Robert B., “New Wine in Old Bottles: Certificate of Need Enters the 1990s,” *Journal of Health Politics, Policy, and Law*, Vol. 18, No. 4, Winter 1993.
- Irvin, Renee A., “Quality of Care Differences by Ownership Form: Implications for Cost Efficiency Studies,” draft prepared for the American Society for Artificial Internal Organs annual conference, April 1998.
- Kiel, Joan M., “How State Policy Affects Rural Hospital Consortia: The Rural Health care Delivery System,” *The Milbank Quarterly*, Vol. 71, No. 4, 1993.
- Lanning, Joyce A., Michael E. Morrissey, Robert L. Ohsfeldt, “Endogenous Hospital Regulation and Its Effects on Hospital and Non-Hospital Expenditures,” *Journal of Regulatory Economics*, Vol. 3:137-154, 1991.
- Lewin/ICF and Alpha Center, “Evaluation of the Ohio Certificate of Need Program,” Executive Summary, June 28, 1991.
- Luft, Harold S., Deborah W. Garnick, David H. Mark, and Stephen J. McPhee, *Hospital Volume, Physician Volume, and Patient Outcomes: Assessing the Evidence*, Ann Arbor, MI, Health Administration Press, 1990.
- McGinley, Patrick John, “Beyond Health Care Reform: Reconsidering Certificate of Need Laws in a Managed Competition System,” *Florida State University Law Review*, 1995.
- Mendelson, Daniel M., and Judith Arnold, “Certificate of Need Revisited,” *Spectrum*, Winter 1993.
- National Home Care Association Newsletter*, “More Than 1,100 Agencies Close; Full Effects of IPS Still Not Felt,” July 1998.
- Pennsylvania Legislative Budget and Finance Committee, “Review of the Certificate of Need Program,” Legislative Budget and Finance Committee, Harrisburg, November 1996.
- Rettig, Richard A., “Dialysis in Connecticut,” *American Journal of Kidney Diseases*, Vol. XIX, No. 6, June 1992
- Salkever, D.S., and T.W. Bice, “Certificate of Need Legislation and Hospital Costs,” in *Hospital Cost Containment*, M. Zubkoff, I.E. Raskin, and R.S. Hanft, eds., New York City, Prodist, 1978.
- Sloan, Frank A., “Containing Health Expenditures: Lessons Learned from Certificate of Need Programs,” in Frank A. Sloan, James F. Blumstein, and James M. Perrin, eds., *Cost*,

Quality, and Access in Health Care: New Roles for Health Planning in a Competitive Environment, San Francisco, Jossey-Bass, 1988.

State of Washington Joint Legislative Audit and Review Committee, “Effects of Certificate of Need and Its Possible Repeal,” Report 99-1, January 1999.

U.S. General Accounting Office, “Medicare Home Health Benefit: Impact of Interim Payment System on Agency Closures and Access to Services,” Washington, D.C., September 1998.

Virginia Joint Commission on Health Care, “Study of Virginia’s Certificate of Public Need (COPN) Program Pursuant to HB 1032 of 1996,” House Document No. 82, 1997.

Weaver, Judith A., “Certificate of Need: What Role Does it Have in a Managed Care Environment?” in Ellis G. Gosfield, ed., *Health Law Handbook*, 1995, pp. 409-429.

Appendix

	8 Year Cumulative			New SMFP More or Less Restrictive	Changes	
	Approve	Deny	% Denied		Current SMFP	Proposed SMFP
Inpatient Hospitals/Beds						
Establish a General Hospital and Addition of Acute Care Beds to an Existing Facility	12	6	33.3%	Less Restrictive	Requires 85% minimum occupancy of beds in planning district to add beds.	Requires 70% minimum occupancy of beds in planning district to add beds.
				Less Restrictive	Beds to be replaced off-site need to have been 85% occupied. This criterion was set aside in 2003.	Beds to be replaced off-site need to have been 70% occupied. Addresses set aside.
				Less Restrictive	Uses a factor of 0.85 in calculating need for med/surg beds.	Uses a factor of 0.80 in calculating need for med/surg beds.
				Less Restrictive	Requires hospitals within 10 miles of a site proposed for relocation of beds have med/surg occupancy of 85% and ICU occupancy of 65%. This criterion was set aside in 2003.	Requires hospitals within 30 minute drive of a site proposed for relocation of beds have med/surg occupancy of 85% and ICU occupancy of 65%. Addresses set aside.
Establish a Long Term Acute Care Hospital	1	1	50.0%	Less Restrictive	Requires 85% minimum occupancy of beds in planning district to add beds.	Requires 70% minimum occupancy of beds in planning district to add beds.
				Less Restrictive	Beds to be replaced off-site need to have been 85% occupied. This criterion was set aside in 2003.	Beds to be replaced off-site need to have been 70% occupied. Addresses set aside.
				Less Restrictive	Uses a factor of 0.85 in calculating need for med/surg beds.	Uses a factor of 0.80 in calculating need for med/surg beds.
				Less Restrictive	Requires hospitals within 10 miles of a site proposed for relocation of beds have med/surg occupancy of 85% and ICU occupancy of 65%. This criterion was set aside in 2003.	Requires hospitals within 30 minute drive of a site proposed for relocation of beds have med/surg occupancy of 85% and ICU occupancy of 65%. Addresses set aside.
Establish a Rehabilitation Hospital and Addition of Rehab Beds and Introduction of Rehab Services at an Existing Facility	3	2	40.0%	More Restrictive	Uses a factor of 0.85 in calculating need for rehab beds. This criterion was set aside in 2004.	Uses a factor of 0.90 in calculating need for rehab beds. Change affirms criterion over the set aside.

Establish a Psychiatric Facility and Addition of Psychiatric Beds to an Existing Facility and Introduction of Psychiatric Services at an Existing Facility and Establish a Substance Abuse Treatment Facility	19	0	0.0%	Less Restrictive	Uses a factor of 0.90 in calculating need for psych and substance abuse treatment beds in planning districts with existing psych and/or substance abuse beds.	Uses a factor of 0.75 in calculating need for psych and substance abuse treatment beds in planning districts with existing psych and/or substance abuse beds.
				Less Restrictive	Uses a factor of 0.90 or 0.80 (depending on average census) in calculating need for psych and substance abuse treatment beds in planning districts without existing psych and/or substance abuse beds.	Uses a factor of 0.80 in calculating need for psych and substance abuse treatment beds in planning districts without existing psych and/or substance abuse beds.
				Less Restrictive	Requires psych and/or substance abuse treatment beds (in units larger than 20 beds) in a planning district to have an average occupancy of 85% before beds can be added in the planning district.	Allows facility specific consideration for a well utilized facility or for geographic remoteness.
				Less Restrictive	Uses a factor of 0.90 in calculating need for intermediate care substance abuse treatment beds in planning districts with existing intermediate care substance abuse beds.	Uses a factor of 0.75 in calculating need for intermediate care substance abuse treatment beds in planning districts with existing intermediate care substance abuse beds.
				Less Restrictive	Uses a factor of 0.90 or 0.80 (depending on average census) in calculating need for intermediate care substance abuse treatment beds in planning districts without existing intermediate care substance abuse beds.	Uses a factor of 0.75 in calculating need for intermediate care substance abuse treatment beds in planning districts without existing intermediate care substance abuse beds.
Obstetrical Services/Beds						
Introduction of Obstetrics Services at an Existing Facility	2	0	0.0%	Less Restrictive	Ob services should be within <i>one hour</i> drive of 95% of the population in rural areas and within <i>30 minutes</i> of 95% of the population in urban areas.	Ob services should be within <i>30 minutes</i> drive of 95% of the population.
				Less Restrictive	Ob programs in urban/suburban areas should perform 3,000 deliveries per year. Set aside in 2003.	Ob programs in urban/suburban areas should perform 2,500 deliveries per year. Addresses set aside.

				Less Restrictive	Ob programs in rural areas should perform 1,000 deliveries per year.	No minimum delivery volume is set for Ob programs in rural areas.
Intermediate Care Facility for Mental Retardation						
Establish an ICF/MR and Addition of ICF/MR Beds	28	0	0.0%	Less Restrictive	Sets maximum size for an ICF/MR at 4 beds.	Establishes no maximum bed size for ICF/MRs. Changes to the Code of Virginia in 2004 exempt ICF/MRs of less than 13 beds from COPN.
Surgical services/ORs						
Establish an Outpatient Surgical Hospital	33	14	29.8%	No Change		
Addition of Operating Rooms to an Existing Facility	33	2	5.7%	No Change		
Introduction of Open-Heart Surgery at an Existing Facility	3	1	25.0%	Less Restrictive	Requires open heart surgery services to be within a two hour drive time of 90% of the population of Virginia.	Requires open heart surgery services to be within one hour drive of 95% of a planning district.
				Less Restrictive	Requires reasonable projection of a minimum patient volume in each of the first three years of operation.	Requires reasonable projection of a minimum patient volume in each of the first two years of operation.
				Less Restrictive	Requires 225 open heart procedures be projected for the second year of operation.	Requires 200 open heart procedures be projected for the second year of operation.
				Less Restrictive	Requires the volume of new programs not reduce the volume of existing programs to less than 760 procedures per year.	Requires the volume of new programs not reduce the volume of existing programs to less than 400 procedures per year.
Introduction of an Organ Transplant Program	1	0	0.0%	Less Restrictive	Requires successful applicants to achieve minimal volume and survival standards and allows revocation of COPN from programs failing to do so.	No provision for revocation of COPN.
				More Restrictive	Requires the following minimum transplant volumes, by organ: Kidney 25 Heart 12 Heart/Lung 12 Liver 12 set aside 1999 Pancreas 12	Requires the following minimum transplant volumes, by organ: Kidney 30 Heart 17 Heart/Lung 12 Liver 21 addresses set aside Pancreas 12 includes kidney/pancreas And adds: Lung 12 Intestine 2

				More Restrictive	Requires the following minimum survival rates, by organ: Kidney 90-95% Heart 70-80% Heart/Lung none set Liver 50-60% Pancreas 80-90%	Requires the following minimum survival rates, by organ: Kidney 95% Heart 85% Heart/Lung 60% Liver 86% Pancreas 90% includes kidney/pancreas And adds: Lung 77% Intestine 77%
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Nursing Homes and Nursing Home Beds

Establish a Nursing Home and Addition of Nursing Home Beds to an Existing Facility and Introduction of Nursing Facility Services in an Existing Acute Care Facility	83	30	26.5%	Less Restrictive	Requires beds to be available within 45 minute drive of 90% of population of Virginia.	Requires beds to be available within 60 minute drive of 95% of population of planning region.
				Less Restrictive	Requires beds in planning district be 95% occupied to determine need.	Requires beds in planning district be 93% occupied to determine need.
				Less Restrictive	In rounding need forecasts only 6 divisions are used.	In rounding forecasts 9 divisions are used, adding opportunities for planning districts with a high calculated need.
				Less Restrictive	Requires a minimum nursing home size of 120 beds.	Requires a minimum nursing home size of 90 beds.
				More Restrictive	Limits nursing home beds in continuing care retirement communities to not more than 20% of the number of non-nursing home beds.	Limits nursing home beds in continuing care retirement communities to not more than 10% of the number of non-nursing home beds.
				Less Restrictive	Replacement projects must demonstrate operating costs of new facility will be comparable to old facility over life of replacement facility	Replacement projects given consideration for improved efficiency, aesthetics and comfort.
				Less Restrictive	Requires all beds at the applicant facility to be 95% occupied before beds can be added.	Requires that all beds in the planning district be 93% occupied before beds can be added.

The proposed changes result in an overall less restrictive regulatory environment for nursing homes.

Diagnostic Imaging

Establish a Diagnostic Imaging Facility	27	13	32.5%	More Restrictive	Disallows any new CT within 30 minutes drive of a CT that performed less than 3,500 HECTS or 3,000 scans.	Disallows any new CT within 30 minutes drive of a CT that performed less than 3,000 scans.
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				Less Restrictive	Requires MRI services to be within 45 minutes drive time of 95% of the population.	Requires MRI services to be within 30 minutes drive time of 95% of the population of the planning district.
				More Restrictive	Requires all MRIs <i>within 45 minutes drive of a proposed MRI</i> to have performed at least 3,500 scans in the previous year.	Requires all MRIs <i>in the planning district</i> to have performed 4,000 scans in the previous year.
				Less Restrictive	Allows consideration of low volume MRIs proposed to be located more than 45 minutes drive from other existing MRIs.	Allows consideration of low volume MRIs proposed to be located more than 30 minutes drive from other existing MRIs.
				Less Restrictive	Offered specific criteria for mobile MRI.	No mobile specific criteria.
				Less Restrictive	Requires that PET services be reviewed on a planning <i>region</i> basis.	Requires that PET services be reviewed on a planning <i>district</i> basis.
				No change	Bases need for PET services on <i>cardiac</i> program volume.	Bases need for PET services on <i>oncology</i> program volume.
				Less Restrictive	Requires all PET scanners in a planning region to have performed 1,500 scans in the previous year before PET capacity can be added. This criterion was set aside in 2002.	Requires all PET scanners in a planning district to have performed 1,200 scans in the previous year before PET capacity can be added. Addresses the set aside.
Addition of Computed Tomography (CT) Equipment at an Existing Facility and Introduction of CT Services at an Existing Facility	52	3	5.5%	More Restrictive	Disallows any new CT within 30 minutes drive of a CT that performed less than 3,500 <i>HECTS</i> or 3,000 scans.	Disallows any new CT within 30 minutes drive of a CT that performed less than 3,000 scans.
				Less Restrictive	Requires CT services seeking to add capacity to have performed 5,000 <i>HECTS</i> or 4,500 scans on each of the existing CTs operated by the service.	Requires CT services seeking to add capacity to have performed 3,000 scans on each of the existing CTs operated by the service.
Addition of Magnetic Resonance Imaging (MRI) Equipment at an Existing Facility and Introduction of MRI Services at an Existing Facility	62	3	4.6%	Less Restrictive	Requires MRI services to be within 45 minutes drive time of 95% of the population.	Requires MRI services to be within 30 minutes drive time of 95% of the population of the planning district.
				More Restrictive	Requires all MRIs <i>within 45 minutes drive of a proposed MRI</i> to have performed at least 3,500 scans in the previous year.	Requires all MRIs <i>in the planning district</i> to have performed 4,000 scans in the previous year.

				Less Restrictive	Allows consideration of low volume MRIs proposed to be located more than 45 minutes drive from other existing MRIs.	Allows consideration of low volume MRIs proposed to be located more than 30 minutes drive from other existing MRIs.
				Less Restrictive	Required specific performance of the applicant's existing MRIs <i>and all MRIs in the planning district</i> (4,000 scans each) to add MRI capacity.	Requires that the applicant's existing MRIs performed 4,000 scans in the previous year to add MRI capacity.
				Less Restrictive	Offered specific criteria for mobile MRI.	No mobile specific criteria.
Addition of Positron Emission Tomography (PET) Services at an Existing Facility and Introduction of PET Services at an Existing Facility	32	1	3.0%	Less Restrictive	Requires that PET services be reviewed on a planning <i>region</i> basis.	Requires that PET services be reviewed on a planning <i>district</i> basis.
				No change	Bases need for PET services on <i>cardiac</i> program volume.	Bases need for PET services on <i>oncology</i> program volume.
				Less Restrictive	Requires all PET scanners in a planning region to have performed 1,500 scans in the previous year before PET capacity can be added. This criterion was set aside in 2002.	Requires all PET scanners in a planning district to have performed 1,200 scans in the previous year before PET capacity can be added. Addresses the set aside.
Non-Cardiac Nuclear Imaging				Less Restrictive	Requires SPECT services to be within 45 minutes drive time of 95% of the population.	Requires SPECT services to be within 30 minutes drive time of 95% of the population of the planning district.
Magnetic Source Imaging				No change	No standards set.	No standards set, technology undeveloped.
The proposed changes result in an overall less restrictive regulatory environment for diagnostic imaging.						
Radiation Therapy						
Establish a Radiation Therapy Facility and Addition of Radiation Therapy Equipment at an Existing Facility and Introduction of Radiation Therapy at an Existing Facility	11	3	17.9%	Less Restrictive	Formula for calculating the need for radiation therapy machines assumes 45% of cancers are treatable with radiation therapy	Formula for calculating the need for radiation therapy machines assumes 60% of cancers are treatable with radiation therapy
				Less Restrictive	Provides consideration for radiation therapy services located at least 60 minutes drive from other radiation therapy services if reasonable projections are made that the service will perform 6,000 treatments by the <i>third year</i> of operation.	Provides consideration for radiation therapy services located at least 60 minutes drive from other radiation therapy services if reasonable projections are made that the service will perform 4,500 treatments by the <i>second year</i> of operation.

				Less Restrictive	All radiation therapy machines operated by an applicant must have an annual treatment volume of 9,000 before addition machines can be added.	All radiation therapy machines operated by an applicant <i>in a planning district</i> must have an annual treatment volume of 8,000 before addition machines can be added.
Introduction of Stereotactic Radiosurgery in an Existing Facility	3	0	0.0%	Less Restrictive	Requires that Stereotactic Radiosurgery services (Gamma Knife) be reviewed on a <i>statewide</i> basis.	Requires that Stereotactic Radiosurgery services (Gamma Knife) be reviewed on a <i>planning region</i> basis.
				Less Restrictive	Requires all stereotactic radiosurgery services <i>in the State</i> to have performed an average of 475 treatments per year before a new service can be authorized.	Requires all stereotactic radiosurgery services <i>in the planning region</i> to have performed an average of 350 treatments per year before a new service can be authorized.
Cardiac Catheterization						
Establish a Cardiac Catheterization Center and Addition of Cardiac Catheterization Equipment at an Existing Facility and Introduction of Cardiac Catheterization Services at an Existing Facility	28	2	6.7%	Less Restrictive	Requires catheterization services to be within 60 minutes drive of 90% of the population of Virginia.	Requires catheterization services to be within 60 minutes drive of 95% of the population of a <i>planning district</i> .
				Less Restrictive	Requires reasonable projection of a minimum patient volume in each of the first three years of operation.	Requires reasonable projection of a minimum patient volume in each of the first two years of operation.
				More Restrictive	No minimum patient volume requirement for a mobile catheterization service.	Establishes a minimum annual patient volume for each of the first three years of operation of a mobile catheterization service.
				Less Restrictive	Requires reasonable projection of a minimum patient volume in each of the first three years of operation for the alternative review method for services in rural areas.	Requires reasonable projection of a minimum patient volume in each of the first two years of operation for the alternative review method for services in rural areas.
				Less Restrictive	Requires reasonable projection of a minimum patient volume in each of the first three years of operation for the addition of catheterization capacity.	Requires reasonable projection of a minimum patient volume in each of the first two years of operation for the addition of catheterization capacity.
				Less Restrictive	Requires reasonable projection of a minimum patient volume in each of the first three years of operation for pediatric catheterization services.	Requires reasonable projection of a minimum patient volume in each of the first two years of operation for pediatric catheterization services.

				Less Restrictive	Requires catheterization services that include interventional catheterizations to have <i>cardiac surgery available on site</i> .	Requires <i>cardiac surgery to be available within a 15 minute drive</i> time of a catheterization service performing interventional catheterizations.
				Less Restrictive	Establishes a projection of a minimum patient volume to be performed by each individual performing catheterizations.	No projection of a minimum patient volume to be performed by each individual performing catheterizations required.
				Less Restrictive	Enumerates basic services that a facility providing catheterization services should offer.	Drops requirement to address the list of basic and common services.

The proposed changes result in an overall less restrictive regulatory environment for cardiac catheterization.

Lithotripsy

Addition of Lithotripsy Equipment at an Existing Facility and Introduction of Lithotripsy Services at an Existing Facility	20	3	13.0%	Less Restrictive	Allows a wait time for lithotripsy services of up to <i>two weeks</i> .	Allows a wait time for lithotripsy services of up to <i>one week</i> .
				More Restrictive	No proximity standard set.	Requires lithotripsy services to be within 30 minutes drive in urban areas and 45 minutes for [rural areas] for 95% of the population of the planning region.
				More Restrictive	Consideration is given to facilities leasing lithotripsy equipment if they had referred <i>72</i> patients per year for the service.	Consideration is given to facilities leasing lithotripsy equipment if they had referred <i>100</i> patients per year for the service.
				Less Restrictive	Requires all lithotripsy machines in the planning region to average <i>1,750</i> treatments per year before a new service can be started.	New service can be started if the lithotripsy machine can demonstrate that a volume of <i>750</i> treatments will be achieved per year.
				Less Restrictive	Lithotripsy capacity can be added only when the average utilization of the applicant's existing lithotripsy machines is <i>2,000</i> treatments.	Lithotripsy capacity can be added only when the average utilization of the applicant's existing lithotripsy machines is <i>750</i> treatments.

The proposed changes result in an overall less restrictive regulatory environment for lithotripsy.

Neonatal Special Care Services

Neonatal Special Care Services	0	0	na	No change	Establishes that a regional perinatal center should have a minimum of <i>15 "beds"</i> .	No minimum bed size established.
				No change	Establishes a ratio of <i>4</i> neonatal special care beds per <i>1,000</i> live births in a perinatal service area.	No bed to birth ratio set.

				No change	Requires neonatal special care units to achieve an average annual occupancy of 85%.	Requires neonatal special care units to achieve an average annual occupancy of 65%.
Miscellaneous Projects						
Miscellaneous Expenditure for Facility Expansion/Renovation	44	0	0.0%	No Change		
Miscellaneous Expenditure for Facility Replacement	6	0	0.0%	No Change		
Miscellaneous Expenditure for Hospital Information Systems	2	0	0.0%	No Change		
Miscellaneous Expenditure for Hospital Parking and Roads	5	0	0.0%	No Change		
Total	522	86	14.1%			

Source: Virginia Department of Health